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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,946	04/11/2005	Motohiro Ohta	03299.000001	8311

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EXAMINER	
WELTER, RACHAEL E	

ART UNIT	PAPER NUMBER
4131	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,946	OHTA ET AL.	
	Examiner	Art Unit	
	RACHAEL WELTER	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/2/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/6/05 & 2/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

The Examiner acknowledges receipt of the preliminary amendment filed 2/2/05 wherein the claims were amended to correct dependencies and conform to accepted U.S. practice.

Note: Claims 1-17 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. No English translation of the Certified Copy of the Foreign Priority Application has been received.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on February 2, 2005 and April 6, 2005 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. A signed copy of forms 1449 are enclosed herewith.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 13, & 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The indefiniteness results from the applicant claiming a composition having an improved oral disintegration property (see claims 1 and 13 and claims dependent therefrom). There is no reference in the claims as to what would constitute an improvement. In this context, it seems like the claims could be improper Jepson claims, wherein claims reciting an improvement need to state what the improvement is and the prior art taught. See MPEP 2129. In addition, the applicant recites, "an improved oral disintegration property," which implies there are multiple oral disintegration properties. If this is the case, the applicant must distinguish which oral disintegration property is being improved from the many properties implied by the applicant's claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta et al. (US Publication No. 2004/0047904) in view of Alkire et al. (US Patent No. 5,607,697).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-12 are drawn to a chewable tablet comprising an amino acid and an oral disintegration promoting agent that is preferably sodium starch glycolate or calcium carboxymethylcellulose. In addition, the chewable tablet comprises a saccharide or a sugar alcohol. Furthermore, the tablet disintegrates in 60-150 seconds by saliva after chewing, the amino acid content is 30-85% by weight, and the tablet hardness is 60 N or more. The amino

acid comprises at least one member selected from the group consisting of valine, leucine, and isoleucine and could include a mixture of pure amino acids and a proteolytic mixture.

Determination of the scope and contents of prior art.

Ohta et al teach an intraorally rapidly disintegrable tablet containing a large quantity of amino acid (abstract). The amino acid content is preferably 35-95% by weight (paragraph 0053) and preferably includes branched-chain amino acids, such as valine, leucine, and isoleucine (paragraph 0048). According to Ohta et al, the amino acid can comprise a combination of two or more amino acids selected from the group consisting of branched-chain amino acids (paragraph 0051). In addition, Ohta et al teach that the tablet contains a saccharide such as maltose, lactose, etc (paragraph 0030). Furthermore, the tablet can include the disintegrating agent, carboxymethylcellulose calcium (paragraph 0054). Finally, according to the examples in Ohta et al, the tablet exhibits hardness between 40-59 N.

Ascertaining the differences between prior art and instant claims.

Ohta et al does not teach a chewable tablet and only teaches an intraorally rapidly disintegrable tablet. In addition, the claimed amino acid content overlaps or lies inside ranges taught in Ohta et al. Similarly, the claimed tablet hardness does not overlap but is close to the values in Ohta et al.

Resolving the level of ordinary skill in the pertinent art.

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of

parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention. See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05.

Therefore, one of ordinary skill would be motivated from the disclosure of Ohta et al to optimize amino acid content. Similarly, a prima facie case of obviousness exists when the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ773 (Fed. Cir. 1985). Thus, the tablet hardness range taught in Ohta et al is close enough to the instant claims that a prima facie case of obviousness exists.

In addition, Alkire et al teach a chewable and intraorally disintegrable tablet (column 3, lines 19-22) that can comprise an amino acid,(column 5, line33) a saccharide, (column 6, lines 12-15) and an oral disintegration promoting agent (column 7, lines 14-15). Furthermore, Alkire et al teach a chewable tablet that disintegrates in the mouth in less than 10 minutes and preferably less than one minute (column 10, lines 1-3).

Therefore, one of ordinary skill would be motivated from the disclosure of Alkire et al to substitute a chewable tablet for an intraorally disintegrable tablet. A chewable tablet needs to have qualities that ensure the tablet disintegrates easily. In addition, most rapidly disintegrable tablets are made in a chewable form like Alkire et al. One of ordinary skill would be motivated

to provide a chewable tablet for children who are more willing to chew tablets than swallow solid dosage forms. The unwillingness of a patient to take certain dosage forms is important because it can severely compromise a patient's compliance with a prescribed treatment protocol. In addition, one of ordinary skill would have a reasonable expectation of success by producing a chewable tablet because a chewable tablet already has some disintegrable qualities that render it a suitable dosage for children. Furthermore, changing the hardness of a tablet is an obvious modification and does not change its intended purpose. See MPEP 2143.01.

Thus, claims 1-12 are *prima facie* obvious over the teaching of the combined prior art.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkire et al (US Patent No. 5,607,697) in view of Murakami et al (US Patent No. 6,287,596) and Tiwari et al (*AAPS Pharmsci* 1999; 1(3) article 13).

Claims 13-15 are drawn to a chewable and intraorally rapidly disintegrable tablet which comprises subjecting powder particles comprising an amino acid and oral disintegration promoting agent to compression molding. In addition, the chewable tablet has powder particles which comprise of a saccharide or a sugar alcohol.

Determination of the scope and contents of prior art.

Alkire et al teach a chewable and intraorally disintegrable tablet that comprises an amino acid, a saccharide, and an oral disintegration promoting agent. The teachings of Alkire et al were set forth above in the instant office action.

Ascertaining the differences between prior art and instant claims.

Alkire et al does not disclose a method for manufacturing the chewable and intraorally rapidly disintegrable tablets.

Resolving the level of ordinary skill in the pertinent art.

Murakami et al teach quickly disintegrable tablets that are compression molded. According to Murakami et al, the tablets are highly hard and thus exhibit excellent storage stability in the production and distribution stages (abstract). Furthermore, in a study by Tiwari et al, compression molding was compared to direct compression. Tiwari et al evaluate the application of polyoxyethylene homopolymers in buccal bioadhesive drug delivery device formulations (abstract). According to Tiwari et al, the bioadhesive strength of devices prepared by the compression molding process was greater than those prepared by direct compression (abstract).

Therefore, one of ordinary skill would have been motivated from the disclosures of Murakami et al and Tiwari et al to use compression molding to manufacture intraorally rapidly disintegrable chewable tablets. Because intraorally rapidly disintegrable chewable tablets are sensitive to moisture and less durable, one of ordinary skill would be motivated to use a method of manufacturing the tablets that promotes tablet strength and excellent storage stability. In addition, one of ordinary skill would have a reasonable expectation of success because of the improved properties of the chewable tablets when they are manufactured by compression molding.

Thus, claims 13-15 are *prima facie* obvious over the teaching of the combined prior art.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over Ohta et al (US Publication No. 2004/0047904) in view of Alkire et al (US Patent No. 5,607,697), as applied to claims 1-12 above, and in further view of Crowley (US Patent No. 4,301,149).

Claims 16-17 are drawn to a portable package in which a chewable tablet comprising an amino acid is contained together with a desiccant.

Determination of the scope and contents of prior art.

The teachings of Ohta et al and Alkire et al were set forth above in the instant office action.

Ascertaining the differences between prior art and instant claims.

Ohta et al does not teach a portable package containing the chewable amino acid tablet together with a desiccant.

Resolving the level of ordinary skill in the pertinent art.

Crowley et al teach a pharmaceutical composition for oral administration that is presented in enclosed containers which contain a desiccant (abstract). According to Crowley, the packaged pharmaceutical composition with the desiccant enhances storage stability and prevents ingress of moisture.

Therefore, one of ordinary skill would be motivated from the disclosure of Crowley to use the containers and packaging for a/an chewable or intraorally rapidly disintegrable tablets because of tablet sensitivity to moisture. In addition, one of ordinary skill in the art would

expect that the tablet packaging with the desiccant to have a reasonable level of success because the desiccant would obviously prevent the tablets from disintegrating in the package under humid conditions.

Thus, claims 16-17 are *prima facie* obvious over the teaching of the combined prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11, 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-36, 38-39, 41, 46-47, 49-50, 52-53 of copending Application No. 10/250,863 (claims amended 3/14/08) in view of Alkire et al (US Patent No. 5,607,697), Murakami et al (US Patent No. 6,287,596) and Tiwari et al (*AAPS Pharmsci* 1999; 1(3) article 13). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 35-36, 38-39, 41, 46-47, 49-50, 52-53 in the copending application are drawn to an intraorally rapidly disintegrable tablet comprising amino acids which include valine, leucine, and isoleucine. The amino acid content of the tablet is 50-98% by weight, which overlaps with the range in instant claim 9. In addition, the tablet is manufactured by compression molding and includes a disintegrating agent along with a saccharide or a sugar alcohol.

Although the copending application does not teach a chewable tablet, it is obvious to substitute a chewable tablet for an intraorally rapidly disintegrable tablet in view of Alkire et al. A chewable tablet needs to have qualities that ensure the tablet disintegrates easily. The applicant would also be motivated to design a chewable tablet because children prefer the dosage form. Furthermore, it would be obvious to optimize the amino acid content range. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. .

Because the instant claims 1-9, 11, &13-15 use the word "comprising" as a transitional term, the claims are inclusive or open-ended and do not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

Therefore, an ordinary skilled artisan at the time of the instant application would have found claims 1-9, 11, and 13-15 *prima facie* obvious over claims 35-36, 38-39, 41, 46-47, 49-50, 52-53 of copending Application No. 10/250,863.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 9 of copending Application No. 10/546,439 in view of Alkire et al (US Patent No. 5,607,697), Murakami et al (US Patent No. 6,287,596) and Tiwari et al (*AAPS Pharmsci* 1999; 1(3) article 13). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1, 5-7, & 9 teach a chewable amino acid containing tablet that was manufactured by compression molding. The teachings of Alkire et al, Murakami et al, and Tiwari et al were set forth above in the instant office action.

Because claims 1, 13-15 use the word "comprising" as a transitional term, the claims are inclusive or open-ended and do not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

Therefore, an ordinary skilled artisan at the time of the instant application would have found claims 1 and 13-15 *prima facie* obvious over claims 1, 5-7, 9 of copending Application No. 10/546,439.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-17 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Janet Andres or Cecilia Tsang can be reached at (571) 272-0867 or (571) 272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Andres/

Supervisory Patent Examiner, Art Unit 4131

REW